

FORM PTO-1449 (modified)  
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	0307368	1997-30-0568D2

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant: HANNA et al.

Appl. No.: 10/743,739

Filing Date: December 24, 2003

Date: February 20, 2004

Page

1

of

1

Examiner: Unassigned

Group Art Unit: Unassigned

## U.S. PATENT DOCUMENTS

Examiner's Initials*		Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
GN	AR	5,585,103	12/1996	Raychaudhuri			
GN	BR	5,695,770	12/1997	Raychaudhuri			
	CR						
	DR						

## FOREIGN PATENT DOCUMENTS

		Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract	Translation Readily Available
						Enclosed	No
	ER						
	FR						
	GR						
	HR						
	IR						
	JR						
	KR						

## OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

GN	LR	Hallinan et al., "Aminoacetyl moiety as a potential surrogate for diacylhydrazine group of SC-51089, a potent PGE2 antagonist, and its analogs," <i>J Med Chem</i> , 1996, 39:609-613					
	MR	Oka et al., "PGE2 receptor subtype EP1 antagonist may inhibit central interleukin-1 $\beta$ -induced fever in rats," <i>The American Physiological Society</i> , 1998, R1762-1765.					
	NR	Isaac et al., "Successful treatment of established rat prostate cancer by transforming growth factor-B1 antisense transfected tumor vaccine," <i>J Urology</i> , 1997, 157:270.					
	OR	Murphy et al., "Differential effects of growth hormone and prolactin on murine T cell development and function," <i>J Exp Med</i> , 1993, 178:231-6					
	PR	Richards et al., "Prolactin is an antagonist of TGF-beta activity and promotes proliferation of murine B cell hybridomas," <i>Cell Immunol</i> , 1998, 184:85-91					
	QR	Jiyanin et al., "Clinical application and potential of TGF $\beta$ ," Beijing Institute of Basic Medical Sciences (thesis), May 1997, pp. 135-40					
	RR	Wojtowicz-Praga et al., "Modulation of B16 melanoma growth and metastasis by anti-transforming growth factor beta antibody and interleukin-2," <i>J Immunol</i> , 1996, 156(3):169-175					
	SR	Arteaga et al., "Anti-transforming growth factor (TGF)-beta antibodies inhibit breast cancer cell tumorigenicity and increase mouse spleen natural killer cell activity. Implications for a possible role of tumor cell/host TGF-beta interactions in human breast cancer progression," <i>J Clin Invest</i> , 1993, 92:2569-2576					
	TR	Hofer et al., "Anti-(transforming growth factor beta) antibodies with predefined specificity inhibit metastasis of highly tumorigenic human xenotransplants in nu/nu mice," <i>Cancer Immunol Immunother</i> , 1995, 41:302-306					

Examiner

Gary Bonich

Date Considered:

3/14/06

\*EXAMINER Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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# **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Atty. Dkt. No.: 037003-0307368

Applicant: NABIL HANNA et al.

U.S. Patent Application. No.: 10/743,739

Filing Date: December 24, 2003

Examiner: Gary B. Nickol Group Art Unit: 1642

Date: December 12, 2005

Page 1 of 3

## **U.S. PATENT DOCUMENTS**

Examiner's Initials	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
W	AR 2002/0004052 A1	01/2002	Berd et al.	424	277.1	
	BR 5,514,670	05/1996	Friedman et al.	514	2	08/1993
	CR 5,709,860	01/1998	Raychaudhuri et al. (claims only)	---	---	
	DR 5,932,212	09/1999	Khalaf (first page and the page with column 10 only).	---	---	
	ER 6,197,311	03/2001	Raychaudhuri et al. (claims only)	---	---	

## **FOREIGN PATENT DOCUMENTS**

	Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract		Translation Readily Available	
					Yes	No	Enclosed	No
W	FR WO 9409815 A1	05/1994	WIPO	Segarini et al.				
	GR							

## **OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)**

W	HR	Berd et al. "Induction of cell-mediated immunity to autologous melanoma cells and regression of metastases after treatment with a melanoma cell vaccine preceded by cyclophosphamide," Cancer Research, 1986, 46(5):2572-2577.
	IR	Blondino et al., "The quantitative determination of aspirin and its degradation products in a model solution aerosol," J Pharm Biomed Anal., 1995, 13(2):111-9 (abstract only).
	JR	Brown et al., "Either interleukin-12 or interferon-gamma can correct the dendritic cell defect induced by transforming growth factor beta in patients with myeloma," Br J Haematol. 2004 Jun;125(6):743-8.
	KR	Carbone et al., "Class I-Restricted Processing and Presentation of Exogenous Cell-Associated with Antigen In Vivo," February 1990, 171:377-387.
	LR	Clarke et al., "Lisofylline inhibits transforming growth factor beta release and enhances trilineage hematopoietic recovery after 5-fluorouracil treatment in mice," Cancer Research, 1996, 56(1):105-112.
	MR	Comerci et al., Altered expression of transforming growth factor-beta 1 in cervical neoplasia as an early biomarker in carcinogenesis of the uterine cervix. Cancer. 1996 Mar 15;77(6):1107-14.
	NR	Crispens et al., "Evaluation of the anticancer activities of Tweens 20, 40 and 60 in SJL/J mice," Anticancer Res., 1991, 11(1):407-8 (abstract only).
	OR	De Wever et al., Critical role of N-cadherin in myofibroblast invasion and migration in vitro stimulated by colon-cancer-cell-derived TGF-beta or wounding. J Cell Sci. 2004 Oct 15;117(Pt 20):4691-4703. Epub 2004 Aug 25.
	PR	Dybedal et al., "Transforming growth factor beta (TGF-beta), a potent inhibitor of erythropoiesis: neutralizing TGF-beta antibodies show erythropoietin as a potent stimulator of murine burst-forming unit erythroid colony formation in the absence of a burst-promoting activity," Blood, 1995, 86(3):949-957.
	QR	Hasegawa et al., "Transforming growth factor-beta1 level correlates with angiogenesis, tumor progression, and prognosis in patients with nonsmall cell lung carcinoma." Cancer. 2001 Mar 1;91(5):964-71.
	RR	Hunter et al., "The Adjuvant Activity of Nonionic Block Polymer Surfactants," J. Immunol., 1981, 127(3):1244-1249.
	SR	Jacobsen et al., "Transforming growth factor-beta potently inhibits the viability-promoting activity of stem cell factor and other cytokines and induces apoptosis of primitive murine hematopoietic progenitor cells," Blood 1995, 86(8):2957-2968.
	TR	Kopp et al., "Transforming growth factor beta 2 (TGF-beta 2) levels in plasma of patients with metastatic breast cancer treated with tamoxifen," Cancer Research, 1996, 55:4512-4515.

*Gary B. Nickol*

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FORM PTO-1449 (modified) To: U.S. Department of Commerce (PW FORM PAT-1449) Patent and Trademark Office	Atty. Dkt. No.: 037003-0307388
<b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Applicant: NABIL HANNA et al.
	U.S. Patent Application. No.: 10/743,739
	Filing Date: December 24, 2003
	Examiner: Gary B. Nickol Group Art Unit: 1642
Date: December 12, 2005	Page 2 of 3

UR	Lee et al., "Aberrant expression of Smad4 results in resistance against the growth-inhibitory effect of transforming growth factor-beta in the SiHa human cervical carcinoma cell line," <i>Int J Cancer</i> . 2001 Nov;94(4):500-7.
VR	Lian et al., "Enhanced expression of transforming growth factor-beta isoforms in the neural tube of embryos derived from diabetic mice exposed to cyclophosphamide," <i>Neurosci Lett</i> . 2003 Nov 6;351(1):51-5.
WR	Matar et al., "Mechanism of antimetastatic immunopotentiality by low-dose cyclophosphamide," <i>Eur. J. Cancer</i> , May 2000, 36(8):1060-1068.
XR	Matar et al., "Down regulation of T-cell-derived IL-10 production by low-dose cyclophosphamide treatment in tumor-bearing rats restores in vitro normal lymphoproliferative response," <i>Int Immunopharmacol</i> . 2001 Feb;1(2):307-19.
YR	Matsunaga et al., "Splenic marginal zone lymphoma presenting as myelofibrosis associated with bone marrow involvement of lymphoma cells which secrete a large amount of TGF-beta," <i>Ann Hematol</i> . 2004 May;83(5):322-5. Epub 2003 Nov 11.
ZR	Medrano et al., "Repression of TGF-beta signaling by the oncogenic protein SKI in human melanomas: consequences for proliferation, survival, and metastasis," <i>Oncogene</i> . 2003 May 19;22(20):3123-9.
AAR	Miller et al., "The Purification and Characterization of the Cytochrome d Terminal Oxidase Complex of the <i>Escherichia coli</i> Aerobic Respiratory Chain," <i>J Biol. Chem.</i> , 1983, 258(15):9159-9165 (page 9159 only).
BBR	Mitani, "Molecular mechanisms of leukemogenesis by AML1/EVI-1," <i>Oncogene</i> . 2004, 23(24):4263-9.
CCR	Mitropoulos et al., "Expression of transforming growth factor beta in renal cell carcinoma and matched non-involved renal tissue," <i>Urol Res</i> . 2004 Sep 7 [Epub ahead of print]
DDR	Moore et al., "Introduction of Soluble Protein into the Class I Pathway of Antigen Processing and Presentation," <i>Cell</i> , September 8, 1988, 54:777-785
EER	Morris et al., "Structural properties of polyethylene glycol-polysorbate 80 mixture, a solid dispersion vehicle," 1992, <i>J Pharm Sci</i> . 81(12):1185-8 (abstract only).
FFR	Piestrzeniewicz-Ulanska et al., "Expression and intracellular localization of Smad proteins in human endometrial cancer," <i>Oncol Rep</i> . 2003 Sep-Oct;10(5):1539-44.
GGR	Sacco et al., "Transforming growth factor beta1 and soluble Fas serum levels in hepatocellular carcinoma," <i>Cytokine</i> . 2000 Jun;12(6):811-4.
HHR	Sansilvestri, "Early CD34high cells can be separated into KIThigh cells in which transforming growth factor-beta (TGF-beta) downmodulates c-kit and KITlow cells in which anti-TGF-beta upmodulates c-kit," <i>Blood</i> , 1995, 86(5):1729-1735.
IIR	Schiemann et al., "Transforming growth factor-beta (TGF-beta)-resistant B cells from chronic lymphocytic leukemia patients contain recurrent mutations in the signal sequence of the type I TGF-beta receptor," <i>Cancer Detect Prev</i> . 2004;28(1):57-64.
JJR	Schmolka, "A Review of Block Copolymer Surfactants," <i>J. Am. Oil. Chem. Soc.</i> , 1977, 54(3):110-116.
KKR	Seoane et al., "Integration of Smad and forkhead pathways in the control of neuroepithelial and glioblastoma cell proliferation," <i>Cell</i> . 2004 Apr 16;117(2):211-23.
LLR	Shariat et al., "Preoperative plasma levels of transforming growth factor beta(1) (TGF-beta(1)) strongly predict progression in patients undergoing radical prostatectomy," <i>J Clin Oncol</i> . 2001 Jun 1;19(11):2856-64.
MMR	Shariat et al., "Preoperative plasma levels of transforming growth factor beta(1) strongly predict clinical outcome in patients with bladder carcinoma," <i>Cancer</i> . 2001 Dec 15;92(12):2985-92.
NNR	Shoen-Chen et al., "Serum levels of transforming growth factor beta1 in patients with breast cancer," <i>Arch Surg</i> . 2001 Aug;136(8):937-40.
OOR	Sitnicka et al., "Transforming growth factor beta 1 directly and reversibly inhibits the initial cell divisions of long-term repopulating hematopoietic stem cells," <i>Blood</i> , 1996, 88(1):82-88.

PAT-1449 12/9:

Garcia

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PPR	Subramanian et al., "Targeting endogenous transforming growth factor beta receptor signaling in SMAD4-deficient human pancreatic carcinoma cells inhibits their invasive phenotype1," Cancer Res. 2004 Aug 1;64(15):5200-11.
QQR	Takahashi et al., "Induction of CD8 <sup>+</sup> Cytotoxic T Cells by Immunization with Purified HIV-1 Envelope Protein in ISCOMs," Nature, April 26, 1990, 344:873-875.
RRR	Takiguchi et al., "Profile of cytokines produced in tumor tissue after administration of cyclophosphamide in a combination therapy with tumor necrosis factor," Anticancer Res. 2004, 24(3a):1823-8.
SSR	Weiner et al., "Treatment of multiple sclerosis with cyclophosphamide: critical review of clinical and immunologic effects," Mult Scler. 2002 Apr;8(2):142-54.
TTR	Xi et al., "Dysregulation of the TGF-beta postreceptor signaling pathway in cell lines derived from primary or metastatic ovarian cancer," J Huazhong Univ Sci Technolog Med Sci. 2004;24(1):62-5.
UUR	Xiong et al., "Transforming growth factor-beta1 in invasion and metastasis in colorectal cancer. World J Gastroenterol," 2002 Aug;8(4):574-8.
VVR	Xu et al., "Elevated serum levels of transforming growth factor beta1 in Epstein-Barr virus-associated nasopharyngeal carcinoma patients," Int J Cancer. 1999 Aug 20;84(4):396-9.

Examiner <i>Garcia</i>	Date Considered: 3/14/06
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